

9/4/1996

MRID No. 440331-01

**DATA EVALUATION RECORD**  
**S 71-1(A) - AVIAN SINGLE-DOSE LD<sub>50</sub> TEST**

1. **CHEMICAL:** Benzyl Benzoate PC Code No.: 009501

2. **TEST MATERIAL:** Benzyl Benzoate Purity: 99.4%

3. **CITATION:**

Authors: I.F. van Dreumel and J.B.J Reijnders  
Title: Acute Oral Toxicity Study in Bobwhite Quail with Benzyl Benzoate

Study Completion Date: March 11, 1996

Laboratory: NOTOX, Hertogenbosch, The Netherlands

Laboratory Report ID: 160201

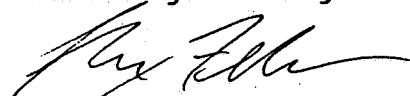
Sponsor: Allergopharma Joachim Ganzer KG, Reinbek, Germany

DP Barcode: D227329

MRID No.: 440331-01

4. **REVIEWED BY:** Max A. Feken, M.S., Environmental Toxicologist, KBN Engineering and Applied Sciences, Inc.

**Signature:**

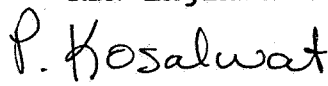


**Date:**

8/13/96

**APPROVED BY:** Pim Kosalwat, Ph.D., Senior Scientist, KBN Engineering and Applied Sciences, Inc.

**Signature:**

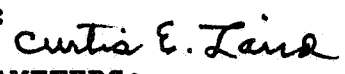


**Date:**

8/13/96

5. **APPROVED BY:**

**Signature:**



**Date:**

9-4-96

6. **STUDY PARAMETERS:**

**Scientific Name of Test Organism:** *Colinus virginianus*

**Test Organisms Age/Size:** 23 weeks/164-224 g

**Definitive Study Duration:** 15 days

7. **CONCLUSIONS:** This study is scientifically sound and fulfills the guideline requirements for an acute oral toxicity test using bobwhite quail. The LD<sub>50</sub> was >2000 mg/kg, which classifies Benzyl Benzoate as practically non-toxic to northern bobwhite. The NOEL was 625 mg/kg.

**Results Synopsis**

LD<sub>50</sub>: >2000 mg/kg

95% C.I.: N/A

NOEL: 625 mg/kg

Probit Slope: N/A

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8. ADEQUACY OF THE STUDY:

- A. Classification: Core
- B. Rationale: N/A
- C. Repairability: N/A

9. GUIDELINE DEVIATIONS: None

10. SUBMISSION PURPOSE:

11. MATERIALS AND METHODS:

A. Test Organisms

Guideline Criteria	Reported Information
<b>Species:</b> A wild waterfowl species, preferably the mallard ( <i>Anas platyrhynchos</i> ), or an upland game bird species, preferably the bobwhite ( <i>Colinus virginianus</i> ).	<i>Colinus virginianus</i>
<b>Age at beginning of test:</b> At least 16 weeks old.	23 weeks
<b>Supplier</b>	Morris Quail Farm Inc., Goulds, FL
<b>Acclimation period:</b> At least 15 days.	At least 14 days

B. Test System

Guideline Criteria	Reported Information
<b>Pen facilities adequate?</b>	Yes
<b>Photoperiod:</b> 10-h light, 14-h dark is recommended.	8-h light; 16-h dark
<b>Diet was nutritious and appropriate for species?</b>	Yes

Guideline Criteria	Reported Information
Feed withheld at least 15 hours prior to dosing?	Food was withheld overnight prior to dosing.

## C. Test Design

Guideline Criteria	Reported Information
Range finding test?	Yes, at 15, 150, 300, 700, and 2000 mg/kg. Various symptoms of toxicity were noted at dose levels greater than 300 mg/kg. One female was found dead at the 2000 mg/kg level.
<b>Definitive Test</b> <b>Nominal concentrations:</b> At least five, in a geometric scale, unless LD <sub>50</sub> > 2000 mg ai/kg.	Control, 195, 625, and 2000 mg/kg.
<b>Controls:</b> Water control or vehicle control (if vehicle is used)	Vehicle (corn oil) control
<b>Number of birds per group:</b> 10 (strongly recommended)	10, 5 male and 5 female
<b>Vehicle:</b> Distilled water, corn oil, propylene glycol, 1% carboxymethylcellulose, or gum arabic.	Corn oil
<b>Amount of vehicle per body weight:</b> Constant volume/weight % of body weight, not to exceed 1% (1 ml/100 g).	Dose volume was equal to 0.5 ml/100 g of body weight.
<b>Observations period:</b> At least 14 days.	15 days

12. REPORTED RESULTS:

Guideline Criteria	Reported Information
Quality assurance and GLP compliance statements were included in the report?	Yes
Individual body weights measured at beginning of test, on day 14 and at end of test if extended beyond 14 days?	Yes
Mean feed consumption measured at beginning of test, on day 14, and at end of test if extended beyond 14 days?	Yes
Control Mortality: Not more than 10%	No mortality during test
Raw data included?	Yes
Signs of toxicity (if any) were described?	Yes

Mortality

Dosage* (mg/kg)	No. of Birds	Cumulative Number of Dead									
		Day of Study									
		1	2	3	4	5	6	7	8	9	10-15
Control	10	0	0	0	0	0	0	0	0	0	0
195	10	0	0	0	0	0	0	0	0	0	0
625	10	0	0	0	0	0	0	0	0	0	0
2000	10	0	0	0	0	0	0	0	0	0	0

\*The dosage of 61 mg/kg was not included in this table since it was added after test initiation.

Other Significant Results: Quick breathing and fluid feces were observed in a few birds at all treatments levels including the control and were not considered treatment related. Various symptoms of toxicity were observed in

birds at the 2000 mg/kg dose level including lethargy, hunched posture, and uncoordinated movement. There was no reduction in food consumption or body weight gain when compared to the control.

Reported Statistical Results

Statistical Method: Visual inspection and Dunnett's test for comparing means (food consumption and body weight)

LD<sub>50</sub>: >2000 mg/kg

95% C.I.: N/A

NOEL: 625 mg/kg

Probit Slope: N/A

**13. VERIFICATION OF STATISTICAL RESULTS:**

Statistical Method: Visual inspection

LD<sub>50</sub>: >2000 mg/kg

95% C.I.: N/A

NOEL: 625 mg/kg

Probit Slope: N/A

- 14. REVIEWER'S COMMENTS:** This study is scientifically sound and fulfills the guideline requirements for an acute oral toxicity test using bobwhite quail. The LD<sub>50</sub> was >2000 mg/kg, which classifies Benzyl Benzoate as practically non-toxic to northern bobwhite. The NOEL was determined to be 625 mg/kg. The study is classified as Core.

DP Barcode : D227329  
 PC Code No : 009501  
 EEB Out :

To: Kathleen Depukat  
 Chemical Review Manager 51  
 Special Review and Reregistration Division (7508W)

From: Anthony F. Maciorowski, Chief  
 Ecological Effects Branch/EFED (7507C)

Attached, please find the EEB review of...

Reg./File # : 009501-059820  
 Chemical Name : Benzyl Benzoate  
 Type Product : Miticide  
 Product Name : Benzyl benzoate  
 Company Name : Allergopharma Joachim Ganzer KG  
 Purpose : Submission of data in support of reregistra-  
 tion of List D, Case No. 4013.

Action Code : 627 Date Due : 09/17/96  
 Reviewer : C. Laird Date In : 06/21/96

EEB Guideline/MRID Summary Table: The review in this package contains an evaluation of the following:

GDLN NO	MRID NO	CAT	GDLN NO	MRID NO	CAT	GDLN NO	MRID NO	CAT
71-1(A)	440331-01	Y	72-2(A)			72-7(A)		
71-1(B)			72-2(B)			72-7(B)		
71-2(A)	440331-02	Y	72-3(A)			122-1(A)		
71-2(B)			72-3(B)			122-1(B)		
71-3			72-3(C)			122-2		
71-4(A)			72-3(D)			123-1(A)		
71-4(B)			72-3(E)			123-1(B)		
71-5(A)			72-3(F)			123-2		
71-5(B)			72-4(A)			124-1		
72-1(A)			72-4(B)			124-2		
72-1(B)			72-5			141-1		
72-1(C)			72-6			141-2		
72-1(D)						141-5		

Y=Acceptable (Study satisfied Guideline)/Concur  
 P=Partial (Study partially fulfilled Guideline but  
 additional information is needed  
 S=Supplemental (Study provided useful information but Guideline was  
 not satisfied)  
 N=Unacceptable (Study was rejected)/Nonconcur

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DP BARCODE: D227329

REREG CASE #

CASE: 287488  
SUBMISSION: S507386

DATA PACKAGE RECORD  
BEAN SHEET

DATE: 06/19/96  
Page 1 of 1

\* \* \* CASE/SUBMISSION INFORMATION \* \* \*

CASE TYPE: REREGISTRATION ACTION: 627 CORE DATA  
CHEMICALS: 009501 Benzyl benzoate

ID#: 009501-059820  
COMPANY: 059820 ALLERGOPHARMA JOACHIM  
PRODUCT MANAGER: 51 KATHLEEN DEPUKAT 703-308-8587 ROOM: CS1 4F6  
PM TEAM REVIEWER: PATRICK DOBAK 703-308-8180 ROOM: CS1 WF34L3  
RECEIVED DATE: 04/16/96 DUE OUT DATE: 07/15/96

\* \* \* DATA PACKAGE INFORMATION \* \* \*

DP BARCODE: 227329 EXPEDITE: N DATE SENT: 06/19/96 DATE RET.: / /  
CHEMICAL: 009501 Benzyl benzoate  
DP TYPE: 101 Phase IV Review

	CSF: N	LABEL: N		
ASSIGNED TO	DATE IN	DATE OUT	ADMIN DUE DATE: 09/17/96	
DIV : EFED	6/20/96	/ /	NEGOT DATE: / /	
BRAN: EEB	7/21/96	/ /	PROJ DATE: / /	
SECT:	/ /	/ /		
REVR :	/ /	/ /		
CONTR:	/ /	/ /		

\* \* \* DATA REVIEW INSTRUCTIONS \* \* \*

Please review the following ecotoxicity studies for the chemical benzyl benzoate, company Allergopharma:  
MRID 44033101 - acute oral toxicity in quail  
MRID 44033102 - 5 day dietary toxicity in quail

\* \* \* DATA PACKAGE EVALUATION \* \* \*

No evaluation is written for this data package

\* \* \* ADDITIONAL DATA PACKAGES FOR THIS SUBMISSION \* \* \*

DP BC	BRANCH/SECTION	DATE OUT	DUE BACK	INS	CSF	LABEL
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100.0 Pesticide Name:

Benzyl Bezoate

100.3 Submission Purpose:

Submission of two avian studies in support of reregistration.

101.0 Chemical and Physical Properties:

101.1 Chemical Name:

Benzyl Benzoate

101.2 Product Name:

Benzyl Benzoate

103.0 Toxicological Properties:

Eight-Day Dietary LC<sub>50</sub> for bobwhite quail  
Acute Oral LD<sub>50</sub> for bobwhite quail

105.0 Conclusions:

A. Bobwhite Quail ( LD<sub>50</sub>) 440331-01

This study is scientifically sound and fulfills the guideline requirements for an acute oral toxicity test using bobwhite quail. The LD<sub>50</sub> was >2000 mg/kg, which classifies Benzyl Benzoate as practically nontoxic to northern bobwhite. The NOEL was 625 mg/kg.

B. Bobwhite Quail (LC<sub>50</sub>) 440331-02

This study is scientifically sound and fulfills the guideline requirements for an acute dietary toxicity test using bobwhite quail. The LC<sub>50</sub> was greater than 5000 ppm, which classifies Benzyl Benzoate as practically nontoxic to bobwhite quail. The NOEC was determined to be 488 ppm. There appeared to be some pesticide related problems at the 1563 ppm dosage level (pale discoloration of the kidney, liver, spleen and spleen reduced in size, reduction in body weight, etc.).

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*Curtis E. Laird* 9-4-96

Curtis E. Laird, Fishery Biologist  
Ecological Effects Branch  
Environmental Fate and Effects Division (7507C)

*Norman J. Cook* 09-05-96

Norman J. Cook, Head-Section #2  
Ecological Effects Branch  
Environmental Fate and Effects Division (7507C)

*Daniel Reider* 9-5-96

Daniel Reider, Acting Chief  
Ecological Effects Branch  
Environmental Fate and Effects Division (7507C)